UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

July 24, 2000

MEMORANDUM

SUBJECT: Diclofop-Methyl (110902). Reregistration Case No.2160.
Registrant's Response to Confined Rotational Crop Data. DP Barcode D266781.

FROM: Sheila Piper, Chemist
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THROUGH: F.B.Suhre, Branch Senior Scientist
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TO: Todd Peterson, Chemical Review Manager
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and
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In support of diclofop-methyl reregistration, Aventis CropScience submitted a letter responding to deficiencies cited in the HED review (S.Piper, D200892, 3/21/00) of an confined rotational crop study (MRIDs 42271901 and 42511601). Deficiencies cited in HED's review are restated below, followed by Aventis' response and HED's comments and conclusions:

Deficiency #1 cited in the confined rotational crop study (D200892):

The submitted confined rotational crop study is adequate pending submission of sample storage information and storage stability data. Crop samples were stored for up to 15 months at -20ºC prior to radioanalysis. Information on sample storage conditions and intervals following radioassays are required along with data

showing the stability of ^{14}C-residues in frozen storage.

Registrant's response to deficiency #1:

Only the soil samples in the confined rotational crop study, analysis of which is no longer required under current guidelines, were retained for periods in excess of 500 days prior to analysis. Plant samples were analyzed by 172 days post-harvest or less. This period is within the current guidelines for plant metabolism studies which require analysis within 4-6 months. Additionally, the wheat metabolism study clearly demonstrated that the crop residue profile remained unchanged over 3 years.

HED Comments/Conclusion:

The OPPTS Guideline 860.1300 states that for metabolism studies, storage stability data should not normally be required for samples analyzed within 4 or 6 months of collection. The plants samples were analyzed by 172-days for post-harvest samples and demonstrated residue stability in the wheat metabolism study. Therefore, deficiency cited in conclusion #1 is resolved.

Deficiency #2b cited in the confined rotational crop study (D200892):

Radioactive residues were not adequately characterized/identified in crop samples from the 30-day PBI. Solvent extractable fractions from lettuce and barley forage (20-29% TRR; 0.013-0.020 ppm) were not sufficiently identified and could contain potential residues of concern.

Registrant's response to deficiency #2b:

The confined rotational crop study, found significant radioactive residues in control plants grown adjacent to pots treated with [^{14}C]-diclofop methyl labeled in either the dichlorophenyl or the dioxyphenyl rings. Thus Aventis concluded that [^{14}C]-diclofop-methyl treated plants release $^{14}CO_2$ which is subsequently absorbed by the control plants and that the remainder of the ^{14}C residue of the treated plant is likely to be diclofop acid, the only significant soil residue available for uptake and the primary metabolite in plant metabolism studies, and possibly traces of hydroxylated diclofop acid, which was a minor component in the wheat study. In addition, the residues in this bare soil application study were extremely low in root and leafy vegetables where total residues were below the limit of quantitation (0.05 ppm) of the analytical method for existing plant targets (parent,

acid and hydroxy acid) even under these "worst case" conditions. Only in barley were total residues detected in excess of the LOQ and then only at 0.1 ppm under the bare soil, confined conditions.

HED Comments/Conclusion:

The OPPTS Guidelines 860.1300 and 860.1850 state that total toxic residues (TRR) less than <0.01 ppm, requires no additional metabolism work and no plackback restriction will be needed on the label. Solvent extractable fractions from lettuce was 25% of the TRR (0.011 ppm) and barley forage was 20% of the TRR (0.020 ppm) from the 30-day plantback interval. In light of the high levels of radioactivity in control samples, HED concludes that the radiolabeled residues found in lettuce (0.011 ppm) do not warrant additional characterization via chromatographic analysis. Also, the residue level found in barley forage at 0.02 ppm is of little concern since barley forage is not a human consumption item. Therefore, deficiency cited in conclusion #2b is resolved.

Recommendations

As a result of additional information provided by Aventis, HED now supports a 30-day planting plant-back interval for root and tuber vegetables, leafy vegetables and small grains rotated into diclofop-methyl treated soils. No crop rotation restriction is required on diclofop-methyl label.

cc: RF, List B File, S.Piper (CEB1)
RDI: FBSuhre: 7/24/00
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